

DHB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

10/5/99
10/5/99
Certifier <i>[Signature]</i>

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 20 and 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

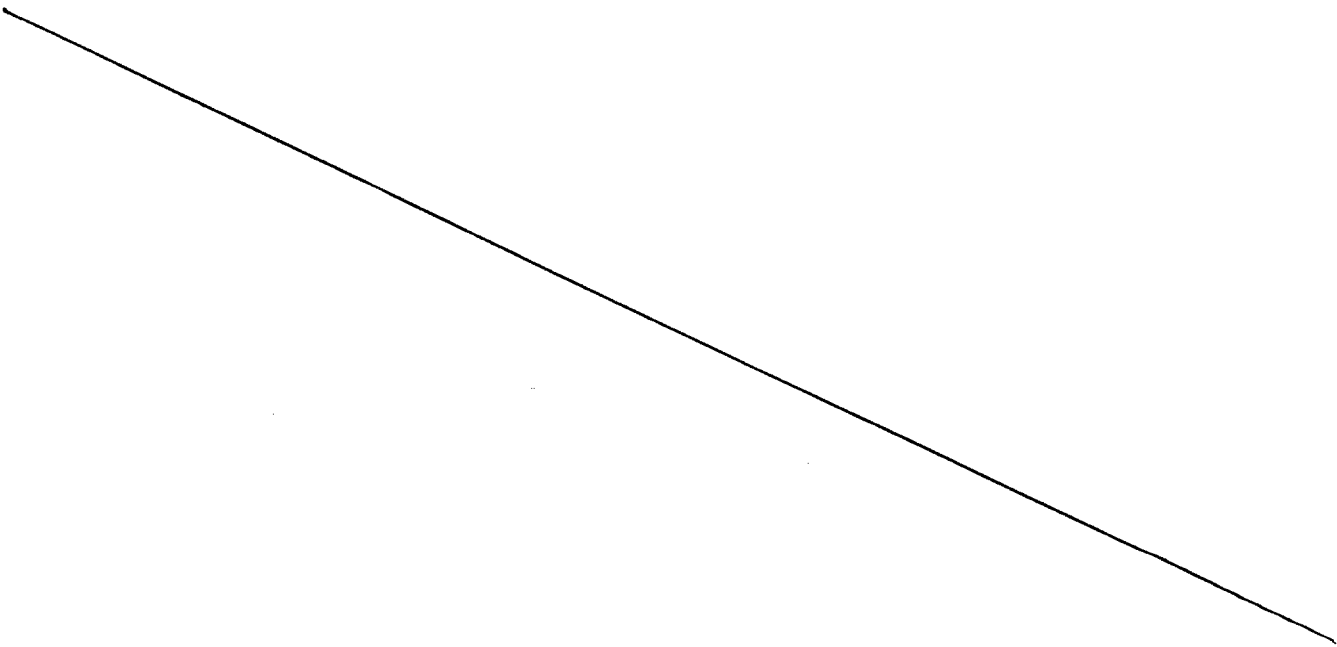
Agenda: On the morning of October 20, 1999, the committee will discuss the development of antimicrobial drugs for the treatment of catheter-related bloodstream infections.

On the afternoon of October 20, 1999, the committee will discuss new drug applications (NDA's) 20-634 and 20-635, levofloxacin (Levaquin™, The R.W. Johnson Pharmaceutical Research Institute) for the treatment of community-acquired pneumonia due to penicillin-resistant *Streptococcal pneumoniae*.

On October 21, 1999, the committee will discuss NDA 21-085, moxifloxacin (Avelox™, Bayer Corp. Pharmaceutical Division), for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, skin and skin-structure infections, and acute sinusitis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1 p.m. and 1:30 p.m. on October 20, 1999, and between approximately 8 a.m. and 8:30 a.m. on October 21, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 20, 1999, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



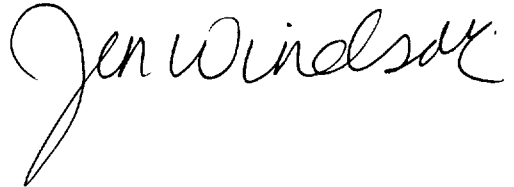
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: September 29, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


Linda A. Suydam
Senior Associate Commissioner



[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F